

Application # 09/966,505  
 Response dated March 9, 2005  
 Reply to Office Action dated September 9, 2004

PATENT  
 P-2776P1PIP1P1

### REMARKS

Claims 1, 12, 13, 19 and 21 have been amended. Claims 16-18 have been withdrawn.

Claims 1-15 and 19-21 are still pending in the present application.

### Claims Rejection – 35 USC § 112

The Examiner states "Claims 1-15 and 19-21 are rejected under 35 U.S.C. § 112 second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention."

Claims 1 and 19 have been amended;

- (i) to make it clear that there are two sensor compositions,
- (ii) to give parallelity to the terms "signal" and "sample".

Claims 12 and 13 have been amended by replacing "A method according to" with "The method of".

Claim 19 has also been amended in order to remove the term "system".

Applicant submits proposed amendments fully address this rejection.

### Claims Rejection – 35 USC § 102

Claims 1-8 and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bacon (Anal Chem) entitled "Determination of Oxygen Concentrations by Luminescence Quenching of a Polymer Immobilized transition Metal Complexes".

This rejection is respectfully traversed.

Of the claims rejected claim 1 is independent, with the remaining claims dependent thereon.

Amended Claim 1 recites, among other things, the following steps:

- (b) *determining the strength of a first said detectable signal generated by said first sensor composition at time intervals*
- (c) *determining the strength of a second said detectable signal generated by said second sensor composition at said time intervals;*
- (d) *comparing the strengths of said first signal with said second signal over said time intervals and determining whether oxygen in said test sample has been consumed*

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Bacon teaches on page 2781 column 2 "Stern-Volmer Calibration Curves" in which the variation of the sensor response depending on whether the sensor was in a gas stream or an aqueous solution was determined. This was done by comparing the lifetime of sensor films in an evacuated, air or oxygen filled bottle with that of the same sensor film in a water-filled bottle that was bubbled with a vigorous stream of nitrogen, air or oxygen.

Applicant respectfully points out Bacon fails to disclose at least the claimed features of: comparing the strengths of a first luminescent signal generated from a first sensor composition exposed to a test sample with a second luminescent signal generated by a second sensor composition exposed to a control sample over time intervals and determining whether oxygen in the test sample has been consumed.

Thus, Bacon does not anticipate claim 1.

For these reasons, applicants submit that amended claim 1 and dependent claims 2-8 and 12 are not anticipated by the Bacon reference.

Claims 1-8 and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wodnicka (J of Biomolecular Screening) entitled "Novel Fluorescent Technology Platform for High Throughput Cytotoxicity and Proliferation Assays".

This rejection is respectfully traversed for the same reasons as discussed above with the Bacon reference.

Of the claims rejected claim 1 is independent, with the remaining claims dependent thereon.

Wodnicka discloses the usefulness of a Fluorescent Oxygen Biosensor technology for cytotoxicity assays, by performing a side by side comparison to standard MTT assays using HL60 cells.

Applicant respectfully points out Wodnicka fails to disclose at least the claimed features of: comparing the strengths of a first luminescent signal generated from a first sensor composition exposed to a test sample with a second luminescent signal generated by a second sensor composition exposed to a control sample over time intervals and determining whether oxygen in the test sample has been consumed.

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Claims 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,080,574 to Berndt ("Berndt").

This rejection is respectfully traversed.

Of the claims rejected claim 19 is independent, with the remaining claims dependent thereon.

Amended Claim 19 recites, among other things, the steps of:

- (c) comparing the strengths of said first signal with said second signal over said time intervals and determining whether oxygen in said test sample has been consumed; and
- (d) indicating to the user if the difference between said first signal and said second signal indicate the consumption of oxygen in the test sample.

Berndt discloses a composite optical blood culture sensor in which a culture medium and blood specimen are introduced into a sealable glass vial having a headspace gas mixture such that a change in the gas mixture composition can be monitored by a chemically sensitive material in the vial comprising a mixture of a fluorophore and a chromophore.

Applicant respectfully points out Berndt fails to disclose at least the claimed features of; comparing the strengths of said first signal with said second signal over the same time intervals and determining whether oxygen in the test sample has been consumed; and then indicating to the user if the difference between the first and second signals indicate the consumption of oxygen in the test sample.

Thus, Berndt does not anticipate claim 1.

For these reasons, applicants submit that amended claim 19 and dependent claims 20 and 21 are not anticipated by the Berndt reference.

### Claims Rejection – 35 USC § 103

Claims 1-15 and 19-21 were rejected under 35 USC 103(a) as being unpatentable over each of Parker (Fiber Optic Sensors) entitled "Chemical Sensors Based on Oxygen Detection by Optical Methods" and U.S. Patent No. 5,998,517 to Gentle, Jr. et al. ("Gentle").

The rejection is respectfully traversed.

The examiner states that;

"The claims differ from each of Parker and Gentle in that they specify a control."

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It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ a control in the method of each of Parker and Gentle because all the data obtained by the methods disclosed by the references are based upon some baseline, such as zero or 100% oxygen. To employ a control in a known assay for its known function with the expected result would have been obvious. Further more no result of the control is presently claimed. Employing computers in luminescence assays is old."

Parker discloses the behavior of fluorophor/polymer composites in the presence of oxygen. The results show that fluorescence quenching as a method of measuring oxygen concentration is rapid and reversible and does not consume oxygen.

Gentle discloses a formulation and method of manufacture for a sensor composition.

The applicant's invention defined by independent claims 1 and 19 is neither taught nor rendered obvious by either Parker or Gentle. Both Parker and Gentle have no suggestion of comparing the strengths of a first luminescent signal generated from a first sensor composition exposed to a test sample with a second luminescent signal generated by a second sensor composition exposed to a control sample over time intervals and determining whether oxygen in the test sample has been consumed.

The Applicant's invention improves the sensitivity of a fluorescence detection system such as those disclosed in Gentle for example, because it enables a researcher to determine whether or not a series of fluorescent signals observed over a period of time for a test sample are greater than for signals from a control sample observed over the same period of time. For particular test samples, oxygen consumption may not be high overall and at any particular time point, a control sample may result in a similar signal to a test sample. The method of the present invention enables similar fluorescent signals from control and test samples to be distinguishable so that over time, one can assess whether or not oxygen consumption occurring in a test sample is different from that occurring in a control sample.

For this reason applicants submit that independent claim 1, dependent claims 2-15 and independent claim 19 and dependent claims 20-21 are not rendered obvious by each of Parker and Gentle references.

Claims 9-11, 13-15 and 19-21 were rejected under 35 USC 103(a) as being unpatentable over Bacon.

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The rejection is respectfully traversed.

The examiner states "The claims differ from Bacon in that they specify different ruthenium salts, the test sample is an enzyme and a computer is employed then assay.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ any known ruthenium salt known for being quenched by oxygen for the same function with the expected results as the specific ruthenium salt as specified by Bacon. No novelty is seen in the presently claimed compounds. Regarding the selection of the sample, no novelty is seen in employing the assay for determining any desired analyte. Employing computers in assays is old."

Bacon teaches only immobilizing [Ru(Ph<sub>2</sub>phen)<sub>2</sub>](ClO<sub>4</sub>) in polymers.

Claims 9-11 and 13-15 are dependent from amended Claim 1 and therefore include all of the limitations of Claim 1. Claims 20 and 21 are dependent from amended claim 19. As discussed above Bacon fails to disclose, teach or suggest the invention of claim 1 and claim 19 as amended i.e. a method for detecting oxygen consumption in a test sample by comparing the strengths of a first luminescent signal generated from a first sensor composition exposed to a test sample with a second luminescent signal generated by a second sensor composition exposed to a control sample over time intervals.

For this reason applicants submit that claims 9-11 and independent claim 19 and dependent claims 20-21 are not rendered obvious by the Bacon reference.

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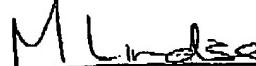
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In view of the remarks and amendments herein, applicants submit the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicant's agent at the telephone number set forth below.

Respectfully submitted,



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Dated: March 9, 2005.

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